(*b*) The batch: A minimum of 5 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately measured representative portion into a high-speed glass blender with sufficient dimethylsulfoxide to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Dilute an aliquot of the stock solution with dimethylsulfoxide to give a concentration of 20 micrograms of amphotericin B per milliliter (estimated). Further dilute an aliquot with 0.2*M* potassium phosphate buffer, pH 10.5 (solution 10), to the reference concentration of 1.0 microgram of amphotericin B per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted suspension.

[39 FR 19134, May 30, 1974, as amended at 50 FR 19920, May 13, 1985]

§ 449.120 Griseofulvin oral dosage forms.

§ 449.120a Griseofulvin tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Griseofulvin tablets are tablets composed of griseofulvin, with or without one or more suitable fillers, colorings, lubricants, and binders. Each tablet contains 125, 250, or 500 milligrams of griseofulvin. The griseofulvin content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of griseofulvin that it is represented to contain. The loss on drying is not more than 5.0 percent. The tablets shall disintegrate within 1 hour. The griseofulvin used conforms to the standards prescribed by § 449.20(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The griseofulvin used in making the batch for griseofulvin content, loss on drying, melting point, specific rotation, identity, residue on ignition, heavy metals, specific surface area, and crystallinity.

(*b*) The batch for griseofulvin content, loss on drying, and disintegration time.

(ii) Samples required:

(*a*) The griseofulvin used in making the batch: 10 packages, each containing not less than 1 gram.

(*b*) The batch for griseofulvin content, loss on drying, and disintegration time.

(b) *Tests and methods of assay*—(1) *Griseofulvin content (gas liquid chromatography).* Proceed as directed in § 436.321 of this chapter, except:

(i) Prepare the sample solution as follows: Accurately weigh 20 tablets and determine the average tablet weight. Grind the tablets to a fine powder in a mortar and transfer an accurately weighed sample to a volumetric flask of such size that for each 50 milliliters of volume there are 40 milligrams of griseofulvin (estimated). Add chloroform to about one-fourth volume of the flask. Swirl the flask and apply gentle heat to aid in dissolution of the griseofulvin. Allow the mixture to cool and then dilute to volume with chloroform and mix. Allow to settle and transfer 2.0 milliliters of the supernate to a conical centrifuge tube and evaporate to dryness under a current of dry air. Add 1.0 milliliter of the internal standard solution to the centrifuge tube and mix vigorously to obtain a uniform solution; and,

(ii) Calculate the milligrams of griseofulvin per tablet as follows:

$$\text{Milligrams of griseofulvin per tablet} = \frac{R_u \times W_s \times f \times W_a \times V_u}{R_s \times W_u \times 1{,}000 \times 50}$$

where:

R_u=Area of the griseofulvin sample peak (at a retention time equal to that observed for the griseofulvin standard)/Area of the internal standard peak;

R_s=Area of the griseofulvin working standard peak/Area of the internal standard peak;

f=Potency of the griseofulvin working standard in micrograms per milligram;

W_a=Average tablet weight in milligrams;

W_s=Weight of the griseofulvin working standard in milligrams;

W_u=Weight of the ground tablet powder sample in milligrams;

V_u=Volume of the dissolved ground tablet powder sample in milliliters.